

Remarks

By the present amendment, claim 7 has been amended to delete the phrase "or prevent". The amendment has been made without prejudice and without acquiescing to the Examiner's objections. Applicant reserves the right to pursue the deleted subject matter in a further application. The amendment does not contain new matter. The Official Action dated February 11, 2003 has been carefully considered. It is believed that the claim amendments and following comments represent a complete response to the Examiner's rejections and place the present application in condition for allowance. Reconsideration is respectfully requested.

Drawings

We are submitting new Figures 2, 3, 4 and 7 in order to respond to the Notice of Draftsperson's Patent Drawing Review. No new matter is contained in the drawings.

35 USC §112, First Paragraph

The Examiner has objected to claims 1 and 4-7 under 35 USC §112, first paragraph because the specification, while being enabling for a method to inhibit lymphoma cell growth and a method to treat lymphoma comprising administering an effective amount of a regulatory T cell having the phenotype CD3⁺ αβ-TcR⁺ CD4⁻CD8⁻CD44⁻ Cd28⁻NK1.1⁻ does not reasonably provide enablement for a method to inhibit any tumor cell growth and a method to treat or prevent any cancer comprising administering an effective amount of a regulatory T cell having the phenotype CD3⁺ αβ-TcR⁺ CD4⁻CD8⁻CD44⁻ Cd28⁻NK1.1⁻. We respectfully disagree with the Examiner for the reasons that follow.

Firstly, as the Examiner has acknowledged, the present application teaches and enables a method of inhibiting lymphoma cell growth and a method of treating lymphoma by administering the regulatory T cells of the invention. We point out that the lymphoma cells used in the present application are a very aggressive form of lymphoma. For example, following the infusion of as few as 10,000 cells, more than 90% of the mice die within 4-5 weeks from a massive lymphoma. Consequently, one

of skilled in the art would readily expect that the regulatory T cells of the invention would be able to kill all types of tumors based on their ability to kill the aggressive lymphoma cells used in the application.

Secondly, there are numerous examples of anti-cancer agents that can treat a wide range of cancers including lymphomas. For example, the most current therapeutic approach for lymphoma is the combined use of doxorubicin, bleomycin, vinblastine and dacarbazine chemotherapeutic drugs. Each of these drugs are also used to treat a variety of other cancers, as follows: Doxorubicin is used in the treatment of leukemias, lymphomas, multiple myeloma, osseous and nonosseous sarcomas, mesotheliomas, germ cell tumors of the ovary or testis, and carcinomas of the head and neck, thyroid, lung, breast, stomach, pancreas, liver, ovary, bladder, prostate, uterus, and neuroblastoma; Bleomycin is used in the treatment of squamous cell carcinomas, melanomas, sarcomas, testicular carcinoma, Hodgkin's lymphoma, and non-Hodgkin's lymphoma; Vinblastine is used in the treatment of Hodgkin's and non-Hodgkin's lymphoma, testicular, lung, head and neck, breast, and renal carcinomas, Mycosis fungoides, Kaposi's sarcoma, histiocytosis, choriocarcinoma, and idiopathic thrombocytopenic purpura; and Dacarbazine is used in the treatment of malignant melanoma, Hodgkin's disease, soft-tissue sarcomas, fibrosarcomas, rhabdomyosarcoma, islet cell carcinoma, medullary carcinoma of the thyroid, and neuroblastoma. Consequently, one who is skilled in the art would expect that an anti-cancer agent that can kill lymphoma cells would also be able to treat other forms of cancer.

Finally, the application is clear in stating that the invention extends to all types of cancer as stated on page 15, lines 11-18 of the application as filed.

In view of the Examiner's objection to the concept of the prevention of cancer, Applicant has deleted this phrase from claim 7.

In view of the foregoing, we respectfully submit that the specification is enabling for the treatment of all types of cancer and request that the objections under 35 USC §112, first paragraph be withdrawn.

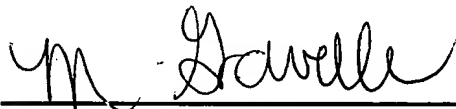
The Commissioner is hereby authorized to charge any fee (including any claim fee) which may be required to our Deposit Account No. 02-2095.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made".

In view of the foregoing comments, we respectfully submit that the application is in order for allowance and early indication of that effect is respectfully requested. Should the Examiner deem it beneficial to discuss the application in greater detail, he is kindly requested to contact the undersigned by telephone at (416) 957-1682 at his convenience.

Respectfully submitted,

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A handwritten signature in dark ink, appearing to read "M. Gravelle", is written over a horizontal line.

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Version with markings to show changes made

In the Drawings:

Figures 2, 3, 4 and 7 presently of record have been replaced with the corresponding Figures submitted herewith.

In the Claims:

7. (Amended) A method according to claim 1 to treat [or prevent] cancer.